REMARKS / ARGUMENTS

I. Amendments to the claims

Claims 8, 9, 11, 40-42 and 44-46 remain in this application and are under examination. Claims 48-52 are added. The Examiner is requested to enter and examine claims 48-52.

Claim 8 is amended to to delete reference to "a fragment comprising at least 12 consecutive amino acids". The claim is also amended to recite --A vaccine vector comprising an isolated nucleic acid molecule--. Basis for the amendment is found at page 10 line 29 to page 11 line 8. Because these amendments do not introduce new matter, entry thereof by the Examiner is requested.

Dependent claims 48-52 are added which specify that the nucleotide sequence encoding SEQ ID No:2 is SEQ ID No:1.

Because these amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested. Applicants retain the right to present claims drawn to the cancelled subject matter in a divisional application(s).

II. Rejection of Claims 8, 9, 11, 39-47 Under 35 U.S.C. §112 first paragraph

The Examiner rejects claims 8, 9 and 11 under 35 U.S.C. §112 first paragraph (enablement), and claims 8, 9, 11, and 39-47 under 35 U.S.C. §112 first paragraph (written description) with respect to fragments. Applicants traverse. The claims have been amended to remove references to fragments. As amended, the claims do meet the requirements of 35 U.S.C. §112 first paragraph.

III. Rejection of Claim 39 Under 35 U.S.C. §112 first paragraph

The Examiner rejects claim 39 under 35 U.S.C. §112 first paragraph (written description). Applicants traverse. The claim is canceled thereby obviating the rejection.

IV. Rejection of the Claims Under 35 U.S.C. § 102(e) -- US patent 6,449,294 ('Griffais')

The Examiner rejects the claims of record under 35 U.S.C. 102(e) as being anticipated by Griffais. Applicants traverse this ground for rejection.

(a) The inventors had possession of SEQ ID No:2 before Griffais' USC 102(e) date

Attached is a Declaration under 37 CFR § 1.131 of inventor Andrew Murdin. Dr. Murdin declares he had possession of SEQ ID No:2 before Griffais' USC 102(e) date (November 4, 1998). He further declares he had possession of the expression construct pCACRMP60 containing a nucleic acid which encodes SEQ ID No:2 before November 4, 1998. Furthermore, Dr. Murdin declares that pCACRMP60 was used to immunize mice before November 4, 1998.

(b) Griffais' disclosure is not enabling for vaccines

Apart from the fact that SEQ ID No:2 was in Applicants' possession before Griffais' USC 102(e) date, Applicants submit that Griffais does not provide an enabling disclosure that would anticipate the pending claims.

(i) What the instant application teaches

The presently amended claims are directed to vaccine vectors comprising a nucleic acid molecule encoding a specific protein (SEQ ID NO: 2) and to pharmaceutical compositions comprising such nucleic acid molecules.

As shown in Examples 1-3 in the specification, nucleic acid vaccines of the invention elicited a protective response against *C. pneumoniae* infection in mice. The specification provides complete details of how to make and use nucleic acid vaccines encoding SEQ ID NO: 2 and demonstrates that such vaccines are indeed useful.

(ii) What Griffais teaches

Griffais sequenced fragments of the *C. pneumoniae* genome and, with the assistance of computer implemented techniques, organized these fragments to create a map of the entire *C. pneumoniae* genome. By analyzing the *C. pneumoniae* genome to identify transcriptional start and stop codons in the *C. pneumoniae* genomic sequence, Griffais identified approximately 1300 putative open reading frames, which might encode proteins (see Table 1 of Griffais).

Using computer-implemented sequence homology analysis, Griffais compared these sequences to those found in sequence databases and, where possible, assigned putative functions to the open reading frames, based on their homology to known sequences.

The experimental work conducted by Griffais ends here.

As discussed in the instant specification, infection by *C. pneumoniae* is a major cause of community acquired pneumonia and perhaps also of other diseases. There is accordingly great interest in a vaccine for the prevention of *C. pneumoniae* infection.

This is of course acknowledged by Griffais, and Griffais provides a generic discussion of how *C. pneumoniae* nucleic acid sequences might be used in the preparation of a vaccine. But while Griffais provides the sequence of the *C. pneumoniae* genome, he does not provide any helpful teaching as to how one might go about actually preparing a DNA vaccine.

(iii) Griffais' disclosure does not teach vaccines

Given the known principles of immunology, it is easy to speculate that one or more proteins expressed by *C. pneumoniae* might be candidates for potential use as a vaccine. This is just what Griffais does. Griffais merely postulates that any of the 1296 putative ORFs might work and then provides a discussion of typical approaches one might use to make a DNA-based vaccine. Griffais does not provide the critical guidance as to which if any of the putative open reading frames might provide a suitable vaccine candidate.

It is clear that Griffais contributes no more to the vaccine art than to offer up the entire genome of *C. pneumoniae*, comprising some 1.2 million nucleotides, and to identify some 1300 potential open reading frames and speculate as to the function of some of them.

(iv) In fact, Griffais' speculation is incorrect -- Only a few of the 1296 open reading frames can be used as vaccines

Applicants have determined that identifying a suitable *C. pneumoniae* sequence for use as a vaccine is no easy matter. Attached is a Declaration under 37 CFR § 1.132 of inventor Andrew Murdin, filed on US 10/334,137. The declaration states that, as part of the assignee's *C. pneumoniae* vaccine programme, 36 *C. pneumoniae* ORFs were tested in the *in vivo* mouse model described in Example 3. Only 8 of the 36 ORFs (i.e. 22%) provided a protective effect.

(v) Griffais' disclosure is not enabling for vaccines

Griffais' contribution is the sequence of the *C. pneumoniae* genome. Griffais does not provide vaccines nor useful teachings as to how to obtain them. Griffais offers no more than a generic description of standard vaccine methodology. Inviting the skilled artisan to search for a solution to the problem effectively by trial and error — in essence searching for the proverbial needle in a haystack — is not an enabling disclosure. A non-enabling reference does not anticipate (*In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). See also *Elan Pharmaceuticals v Mayo Foundation*. US Court of Appeals for the Federal Circuit, 00-1467, decided October 2, 2003:

> The issue is not whether the [prior art] teachings are an accurate compilation of the state of the scientific art at that time, [...] The issue is whether [the prior art] teachings enabled a person of ordinary skill, without undue experimentation, to produce the desired [result].

Based on the teachings of Griffais, considered as a whole (*W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)), the skilled person could not practice the instantly claimed invention without undue experimentation. Griffais therefore does not teach or suggest the instantly claimed subject matter. The insufficiency of the teachings of Griffais is made all the more clear by Applicants' own work showing that relatively few ORFs of *C. pneumoniae* are useful in the preparation of vaccines.

Withdrawal of the rejection under 35 U.S.C. §102(e) in view of Griffais is requested.

V. Concluding Remarks

In view of the above amendments and remarks, reconsideration and favorable action on all pending claims are respectfully requested. If any questions or issues

remain, the Examiner is invited to contact the undersigned at the telephone number set forth below so that a prompt disposition of this application can be achieved.

If a fee is required for an extension of time which is not accounted for, such an extension is requested and the U.S.P.T.O. is authorized to withdraw from our Deposit Account Number 19-0741 any fee required.

Respectfully submitted,

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